Assessment of malnutrition in patients with head and neck cancer: a multidimensional approach

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Chapter 3. Translation and cultural adaptation of the scored Patient-Generated Subjective Global Assessment (PG-SGA): an interdisciplinary nutritional instrument appropriate for Dutch cancer patients

Cancer Nursing, 2018:41(6):450-462.

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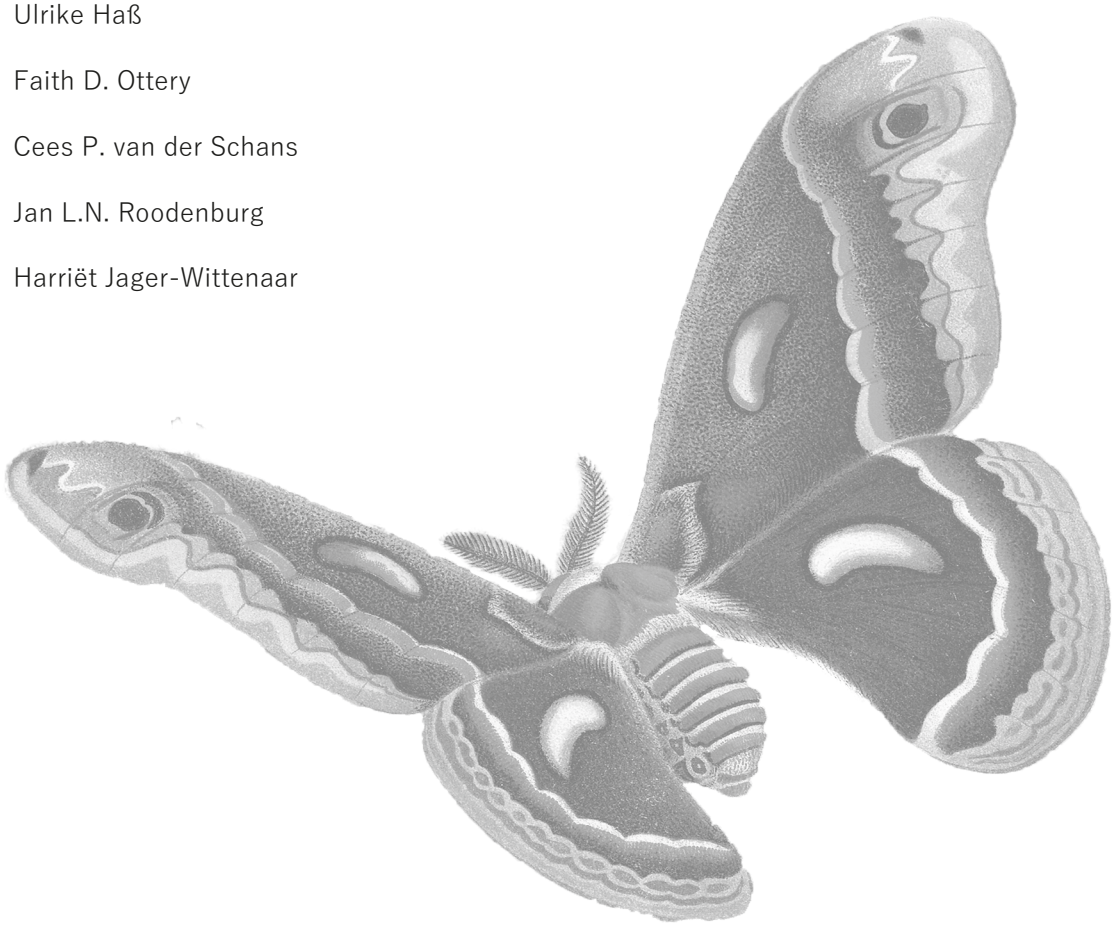

Abstract

Background: The Scored Patient-Generated Subjective Global Assessment (PG-SGA) is an instrument that enables interdisciplinary assessment of malnutrition and its risk factors, which is not available in Dutch.

Objective: Translation and cultural adaption of the original English PG-SGA to the Dutch setting.

Methods: The Scored PG-SGA was translated and culturally adapted, following ISPOR principles. Perceived content validity, comprehensibility and difficulty were explored among a multidisciplinary sample of healthcare professionals and their cancer patients. Content validity, comprehensibility and difficulty were operationalized by calculating item and scale indices. On scale level, indices of 0.80-0.90 were considered acceptable and indices of ≥0.90 were considered excellent.

Results: Consensus was reached on 91 and 8 differences in the forward and back translations respectively. Scale Content Validity Index was 0.89. Scale Comprehensibility Index (S-CI) and Scale Difficulty Index (S-DI) of the patient-generated component of the PG-SGA were 0.99 and 0.96, respectively. S-CI and S-DI of the professional component were 0.81 and 0.55, respectively.

Conclusions: Translation and cultural adaptation of the PG-SGA according to ISPOR principles resulted in a Dutch version that maintained purpose, meaning and format and has acceptable content validity. Now a Dutch version of the PG-SGA is available that is considered comprehensible and easy by patients, and comprehensible and relevant by professionals.

However, the professional component was considered difficult by the PG-SGA naive healthcare professionals, which indicates a need for training of professionals.
Implications for Practice: A similar systematic approach for future translations of the PG-SGA is recommended, to safeguard cultural equivalence.

Introduction

Malnutrition has been defined as "An acute, subacute or chronic state of nutrition, in which a combination of varying degrees of overnutrition or undernutrition and inflammatory activity has led to a change in body composition and diminished function".[1] Patients with cancer who develop malnutrition during the course of their illness are at risk for treatment complications, more frequent and longer hospital stays, reduced quality of life and higher mortality.[2-5] Patients with cancer often have symptoms that may negatively impact nutritional intake, such as loss of appetite, nausea, and fatigue, due to the disease itself or due to treatments such as surgery, chemotherapy and radiotherapy.[6,7] For this reason, patients with cancer are particulary at risk for developing malnutrition. Prevalence of malnutrition in cancer patients is estimated to range from 30 to 60%.[4,8,9] However, these estimations depend on the malnutrition criteria used and on the cancer type and timing of the assessment.[6,10] When there is no effective assessment of malnutrition and its underlying risk factors,[11] malnutrition often goes unrecognized by medical and nursing staff, hindering effective treatment to improve nutritional status.[12,13] To enable more proactive rather than reactive nutritional care for patients with cancer, interdisciplinary collaboration of healthcare professionals that are involved in the nutrition care process, such as nurses, dietitians and physicians, is needed.[14] Hence, a validated

instrument that assesses malnutrition and its underlying risk factors, and that facilitates interdisciplinary care, is required to enable routine provision of appropriate nutritional care for cancer patients.[15]

Scored Patient-Generated Subjective Global Assessment

The Scored Patient-Generated Subjective Global assessment (PG-SGA; Copyright FD Ottery, 1996, 2001, 2005, 2006) is a tool that is recognized widely in the nutritional field and exhibits a unique set of properties: 1) the PG-SGA is reportedly a simple instrument to use[16] and can be used as a nutritional screen and assessment;[17,18] 2) the PG-SGA addresses the full breath of the construct of malnutrition as defined, containing items concerning nutrient balance; body shape, size and composition; function; and inflammatory activity;[1,19] 3) the PG-SGA helps identifying problems that may disguise malnutrition such as imbalance in fluid status;[16] 4) the PG-SGA includes both patient- and professional-reported items, thus providing accumulated insight from both perspectives in the nutritional status of the patient; 5) the PG-SGA identifies specific nutritional impediments allowing personalized medical and nutritional interventions;[20] and 6) the PG-SGA facilitates interdisciplinary planning of the global patient care process by triaging for interventions by nurse, dietitian and/or physician.[14,15] The PG-SGA was first validated in the oncology setting.[18,21-23] It has subsequently been validated in other settings, such as the nephrology and geriatric setting.[24,25] In addition, the PG-SGA has been utilized as a reference method to evaluate nutritional status in patients with cancer. [26-28] The totality of publications worldwide, well over 100 articles as referenced in PubMed with the search term 'PG-SGA', reflects the extensive clinical and research interest in this instrument.[29]

The PG-SGA was developed as a modification of the Subjective Global Assessment tool.[30] The scored version of the PG-SGA consists of two components. First, the patient-generated component was designed to be completed by the patient. For clarity, the items in this component were delineated as four Boxes.[21] Box 1 addresses weight history and addresses intermediate (1 month), chronic (6 months), and acute (2 weeks) weight change. Box 2 addresses food intake, including changes in type, amount and consistency of nutrient intake. Box 3 addresses symptoms and other impediments that may negatively influence food intake. Examples of nutrition impact symptoms can include no appetite, nausea, constipation, and problems with swallowing. Box 4 includes activity and function based on the Eastern Cooperative Oncology Group (ECOG) performance status, converted to layman's language.[31] These four Boxes were designed to reflect approximately 80-90% of the scorefor any given patient, and are officially known as the PG-SGA Short Form (PG-SGA SF), at times referred to in the literature as the abridged PG-SGA.[23] The PG-SGA SF has been validated as an independent screening tool for malnutrition and its risk factors.[17,32]

Second, the items in the professional component were developed as Worksheets to provide self-contained training and raise awareness of contributors to malnutrition that in clinical practice may easily be overlooked, such as metabolic stress, e.g. fever and corticosteroids.[21] The professional component includes five Worksheets and is completed by the healthcare professional; this may include the dietitian, nurse, physician, physiotherapist or others involved in the clinical care of the patient. Worksheet 1 includes instructions on how to score the percentage weight loss relevant to Box 1. Worksheet 2 addresses multiple conditions that may increase nutritional risk or requirements. Additionally, age >65 years was included as a factor

related to risk for malnutrition. Worksheet 3 addresses metabolic stress, based on fever (degree and duration), and use of corticosteroids. Worksheet 4 addresses the scoring of muscle status (i.e., deficit/loss of muscle mass and/or muscle tone), fat stores, and fluid status (specifically fluid excess), based on the nutrition focused physical examination. Worksheet 5 categorizes the overall global assessment of the patient, utilizing the findings of the patient-generated component (Boxes 1-4) and the physical exam (Worksheet 4). Categories include Stage A = Well nourished; Stage B = Moderately malnourished or suspected malnutrition; or Stage C = Severely malnourished.[21]

In contrast to the categorical assessment, the PG-SGA numerical score allows triage for interdisciplinary interventions as well as a means to monitor outcomes of these interventions. The additive score is used to guide interdisciplinary interventions including patient and carer education, symptom management including pharmacologic intervention, and nutritional intervention (food, nutritional supplements, enteral, or parenteral nutrition).

Triage recommendations based on PG-SGA point score are as follows:

0-1 No intervention required at this time. Re-assessment on routine and regular basis during treatment.

2-3 Patient & family education by dietitian, nurse, or other clinician with pharmacologic intervention as indicated by symptom survey (Box 3) and lab values as appropriate.

4-8 Requires intervention by dietitian, in conjunction with nurse or physician as indicated by symptoms (Box 3).

≥ 9 Indicates a critical need for improved symptom management and/or nutrient intervention options.[22]

Rationale for translation and cultural adaptation

Given the ability to identify both malnutrition and its underlying risk factors, as well as providing nutritional triage recommendations that may facilitate tailored interdisciplinary care, in the Netherlands the PG-SGA could provide a valuable addition to the instruments that are currently available, such as Malnutrition Universal Screening Tool (MUST)[33] and Short Nutritional Assessment Questionnaire (SNAQ)[34]. However, the PG-SGA was originally developed in English, and until now an official Dutch translation was not available. To enable use of the PG-SGA in other lingual and cultural settings than the original one, high quality versions of the original English PG-SGA in other languages are needed. However, straight forward translation of the PG-SGA may alter its purpose and meaning, since differences exist between languages, and additionally differences may exist between the corresponding cultures. Cultures comprise ideas, customs and social behavior of a group of people and include their concepts of health and illness and levels of literacy.[35] Differences between the source culture and the target culture may influence the cultural equivalence of an instrument.[36-38] However, if instead a cultural adaptation process for the target culture is employed, several levels of equivalence can be safeguarded.[35,36] Conceptual equivalence refers to the level to which the concept that is measured by the instrument exists, is relevant, and is accepted in both the source culture and the target culture.[39] The degree to which the instrument has an appropriate sample of items for the concept being measured has been defined as content validity.[40] Semantic equivalence is obtained when the meaning of the instrument is maintained in both the target and source language. This implies the items should be perceived equally comprehensible and difficult in the target and the original culture.[35,39] Comprehensibility, i.e.

clarity or understandability, is related to the clarity of the wording used in the instrument. Difficulty is related to the level of knowledge or skills of the person completing the instrument. Additionally, operational equivalence is obtained when the level to which the mode of administration, the format of the instrument, the reading level and the item format are appropriate for the target culture. In this study, we aimed to systematically translate and culturally adapt the original English PG-SGA for the Dutch setting, while safeguarding conceptual, semantic and operational equivalence and including exploration of content validity as perceived by healthcare professionals, and of comprehensibility and difficulty as perceived by patients and healthcare professionals.

Methods

Authorization

We received authorization from the key developer and copyright holder of the PG-SGA to translate the original English PG-SGA into Dutch (reference 9601.2016). All documentations pertaining to the translation, including item history, cognitive debriefing, and decisions made, were made available to the key developer of the PG-SGA. All the translation steps and the final Dutch version of the PG-SGA have been approved by the key developer of the PG-SGA. The Medical Ethics Committee of the University Medical Center Groningen ruled that no permission was needed to perform the study (reference M13.137580), because the study was not under regulation of the Medical Research Involving Human Subjects Act.

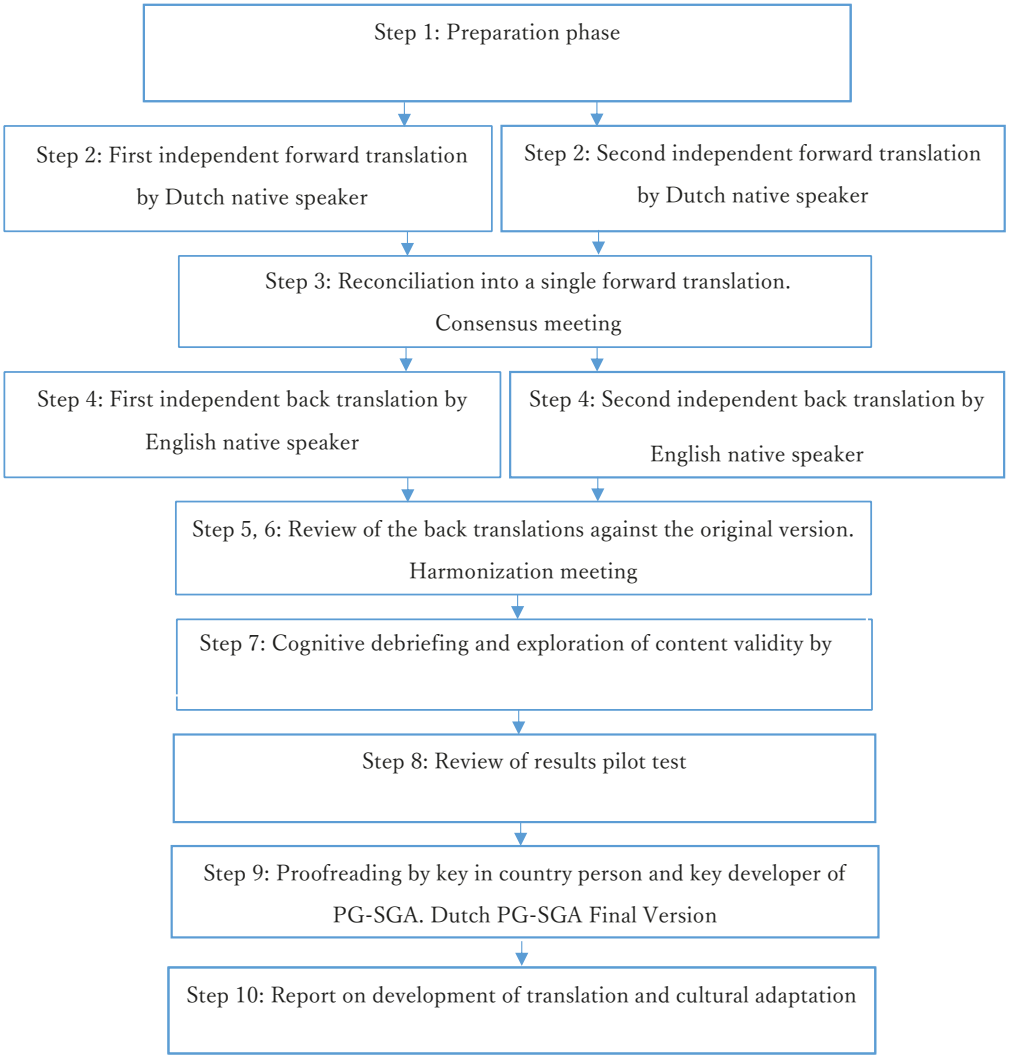

Figure 1. Flowchart of development Dutch PG-SGA ISPOR Principles of Good Practice for the Translation and Cultural Adaption Process for PRO Measures

Procedures

Between February 2013 and August 2014, the Dutch version of the PG-SGA was developed according to the ten steps of the International Society For Pharmacoeconomics and Outcomes Research (ISPOR) *Principles of Good Practice for the Translation and Cultural Adaptation Process for PRO Measures* (further referred to as ISPOR principles)[41] (Figure 1). Conceptual, semantic, and operational equivalence were addressed and tested by following the first nine steps of the ISPOR guideline, to validate the translation and adaptation process.

Step 1 Preparation Phase. During the preparation phase, the project coordinator initiated first contact with the key developer of the original version of the PG-SGA and with professional translators for the forward and back translations.

Step 2 Forward translation. The initiator of the project, further referred to as the 'key country person', provided the first forward translation of a large print version of the PG-SGA (©FD Ottery, 2005), using a landscape orientation. She is a native Dutch speaker with sufficient knowledge of the English language, an experienced dietitian in the cancer setting, and an expert on the subject of nutritional assessment. Additionally, a professional and native Dutch speaking translator with no special knowledge of patients with cancer or nutritional assessment was instructed to conceptually translate the same version of the English PG-SGA and independently provided a second forward translation.

Step 3 Reconciliation. The project coordinator, the key country person, and the corresponding author in the role of independent translator discussed conceptual and semantic differences between the two independent forward translations into Dutch that were the result of Step 2. Both forward translations were compared to the original English version and discussed, until

consensus was reached on all nuances. This step resulted in the first version of the Dutch PG-SGA.

Step 4 Back translation. Two English native-speaking professional translators, of which one of United States origin and one of New Zealand origin, with no special knowledge on the subject of cancer or nutritional status, performed two independent conceptual back translations of the Dutch PG-SGA version that was the result of Step 3 into English.

Step 5, 6 Back translation review and harmonization. These steps were combined in a single panel meeting. The purpose of the back translation review and harmonization was to ensure conceptual and semantic equivalence, and to design a prototype version of the Dutch PG-SGA. All differences between the original English version and the two back translations were discussed in a meeting that was prepared and led by the project coordinator and further attended by the key country person and the corresponding author. Additionally, the Dutch version that resulted from Step 3 (Reconciliation) was adapted if needed, to harmonize with the original English version.

Step 7 Exploration of content validity and cognitive debriefing. In May 2013, two samples, one consisting of Dutch patients and one consisting of Dutch healthcare professionals, were informed about the project, and gave their written consent before participating in the study. Both patients and healthcare professionals had no experience with the PG-SGA. Dietitians, nurse practitioners and medical interns working in the oncology setting and who were inexperienced with the PG-SGA were asked to recruit one of their patients to complete the patient-generated component of the PG-SGA, and to have the patients complete a questionnaire. This 55-item questionnaire included 47 four-point scale items regarding

perceived comprehensibility and difficulty of the items of the patient-generated component of the PG-SGA (Boxes 1 to 4). The remaining eight items of the questionnaire concerned facultative open ended questions to identify potential barriers regarding comprehensibility, difficulty and operational aspects of the PG-SGA.

Subsequently, the healthcare professionals were asked to carefully study the full PG-SGA and complete the professional component (Worksheet 1-5 and numerical score) of the PG-SGA. The professionals were then asked to complete a 134-item questionnaire, consisting of 124 four-point scale items regarding content validity of the items of the full PG-SGA, as well as perceived comprehensibility and difficulty of the items of the professional component of the PG-SGA. The remaining ten items posed to the healthcare professionals concerned facultative open ended questions, to identify potential barriers concerning content validity, comprehensibility, difficulty and operational aspects of the PG-SGA. The distribution of items per concept and component of the PG-SGA is presented in Table 1. For the exploration of content validity, a sample of three to eight healthcare professionals was considered adequate.[40,42] For the cognitive debriefing, a sample of five to eight patients, and a sample of five to eight healthcare professionals was considered adequate.[41]

Step 8 Review of exploration of content validity and cognitive debriefing results. The results of the questionnaire posed to patients and the questionnaire posed to the professionals were reviewed by the project coordinator and the corresponding author.

Table 1. Distribution of questionnaire items related to concepts and PG-SGA components

Concept	Items Patient-generated component	Items Professional component
Content validity	38	26
Comprehensibility	38	34
Difficulty	9	26
Open ended questions	8	10

Step 9 Proofreading and finalization. The key country person and the key developer of the original PG-SGA performed elaborate proofreading on 10 December 2013 and 4 June 2014. During these sessions, operational differences that may influence clarity of the format on scale and item level were discussed and solved.

Step 10 Report on development of translation.

Operationalization of perceived content validity, comprehensibility and difficulty

A widely used approach to quantifying content validity, i.e. perceived relevance, is by reporting the content validity index (CVI).[40,42,43] In this approach, a sample of professionals rates each item of a scale or instrument to be relevant or not, for the construct to be measured. From these ratings, an item content validity index (I-CVI) is calculated that can be averaged into scale content validity indices (S-CVI). The S-CVI of the full PG-SGA reflects overall relevance of the instrument to the construct of malnutrition as perceived by healthcare professionals. The higher the S-CVI, the more consensus on the nature of the construct can be assumed.[40,42] To be able to quantify the concepts of comprehensibility and difficulty, the CVI-approach was

adapted for this study. Indices for item comprehensibility (I-CI)[44] and item difficulty (I-DI) were calculated and averaged into scale comprehensibility indices (S-CI) and scale difficulty indices (S-DI).

The following procedure was used to calculate all item and scale indices: A four point scale (1= very irrelevant/very unclear/very difficult; 2= irrelevant/ unclear/difficult; 3=relevant/clear/easy; 4=very relevant/very clear/very easy) was implemented, to avoid having a neutral and ambivalent midpoint and to dichotomize the results of each item.[40,45] This enabled us to decide whether content validity, comprehensibility and knowledge could be considered present or not for each item. Scores 1 and 2 were considered 'not present', scores 3 and 4 were considered 'present'. The I-CVI, I-CI and I-DI are proportional scores ranging from 0-1, calculated by dividing the number of respondents that considered the item to be 'present' by the total number of respondents. The S-CVI was calculated by averaging the I-CVI scores for the full PG-SGA. S-CI and S-DI of the patient-generated component of the PG-SGA were calculated by averaging I-CI scores and I-DI scores of Boxes 1 to 4. S-CI and S-DI of the professional component of the PG-SGA were calculated by averaging I-CI scores and I-DI scores of Worksheets 1 to 5. The scale indices S-CI and S-DI reflect overall comprehensibility and difficulty, as perceived by patients for the patient-generated component and as perceived by professionals for the professional component.

As predefined, an I-CVI above 0.78 was considered excellent and an I-CVI <0.78 requires further analysis of the item.[43] An S-CVI≥0.80-0.89 was considered acceptable and an S-CVI≥0.90 was considered excellent.[43,46] In agreement with the content validity approach, the same cutoff standards were applied to I-CI, I-DI, and S-CI and S-DI scores. Transparency of

response was provided by reporting overall item response. Patients and healthcare professionals' non-response to items was excluded from the calculation of the index scores. Respectively I-CI, I-DI and I-CVI per item; and S-CI, S-DI and S-CVI per scale were calculated in SPSS (19.0, IBM Inc.).

Results

The forward translation process provided the first two Dutch translations of the PG-SGA. During the reconciliation phase, consensus was reached on the 91 differences (29 patient-reported items and 62 professional-reported items) that were identified between the two forward translations into Dutch. The Dutch documentation of the reconciliation session can be provided upon request by the corresponding author. The back translation and harmonization process resulted in eight additional adaptations (five patient-reported items and three professional-reported items). Documentation of the back translation review and harmonization process is presented in Table 2. The harmonization process resulted in a five page document as prototype of the Dutch version of the PG-SGA.

Eight Dutch healthcare professionals completed the questionnaire developed for the professionals: six dietitians, one nurse practitioner and one medical intern. Within this sample, six healthcare professionals participated with a patient, resulting in six patients completing the questionnaire developed for the patients. The sample of patients consisted of four women and two men (aged 54-73 years) with cancer (head and neck cancer n=4, pancreas cancer n=1, ovarian cancer n=1). Data on difficulty of items of the professional component of the PG-SGA were missing in one healthcare professional.

TABLE 2. Documentation of adaptations made in the back translation review and harmonization meeting

Box	Reconciliation	Translator 1	Translator 2
Box 3 – Symptoms	moeite met slikken	difficulty swallowing	difficulty with swallowing
Box 4 – Activities and functioning	Van de afgelopen maand beoordeel ik mijn activiteiten als	I would assess my activities of the previous months as	Over the past month I would rate my activities as
Box 4 – Activities and functioning	beperkt in zware lichamelijke activiteit, maar ambulant en tot lichte arbeid in staat	limited heavy physical activity, but ambulant and able to perform light work	cannot do heavy physical activities, but moving about and able to do light work
Box 4 – Activities and functioning	slechts tot beperkte zelfverzorging in staat, meer dan 50% van de dag in bed of op stoel	only limited self-care, more than 50% of the day in bed or chair	unable to look after myself, spend more than half the day in bed or on a chair
Worksheet	**Reconciliation**	**Translator 1**	**Translator 2**
Worksheet 5 – Category – Stage B	licht tot matig ondervoed	mild to moderately malnourished	light to moderately malnourished
Worksheet 5 – Category – Stage B and C	aanwezigheid van symptomen die de voedingsinname kunnen verstoren	presence of symptoms that may disrupt the nutritional intake	presence of symptoms that could influence food intake
Worksheet 5-- Physical exam – stage B	duidelijk milde of matige depletie van vetmassa of spiermassa en/of spiertonus bij palpatie	marked mild or moderate depletion of fat mass or muscle mass and/or muscle tone during palpation	clear mild or moderate deficit in fat stores or muscle mass or tone on palpation

Original	Harmonization	Comments
problems swallowing	problemen met slikken	"problemen" implies the symptom is serious enough not to be able to eat. "moeite" could imply it takes more time but does not affect intake
Over the past month, I would generally rate my activity as	Ik beoordeel mijn activiteiten van de afgelopen maand over het algemeen als	to start with "Ik (I)" fits better in Dutch use of language; generally "over het algemeen" was added
restricted in physically strenuous activity but ambulatory and able to carry out light work	beperkt in zware lichamelijke activiteit, maar niet bedlegerig en tot lichte arbeid in staat	"ambulant" appears to difficult. "niet bedlegerig" is clearer to the patient
capable of only limited self-care; confined to bed or chair more than 50% of waking hours	slechts tot beperkte zelfverzorging in staat; meer dan 50% van de dag in bed of stoel	";"interpunction added to clarify "op" deleted
Original	**Harmonization**	**Comments**
moderately malnourished or suspected malnourished	matig ondervoed of verdenking ondervoeding	"verdenking ondervoeding" was changed to "licht tot matig" in the forward translated and is now changed back again
presence of nutrition impact symptoms (box 3 of PG-SGA)	aanwezigheid van symptomen die de voedingsinname verstoren	"kunnen" deleted, symptoms must have actually hindered intake as stated in box 3
evidence of mild to moderate loss of SQ fat &/or muscle mass &/or muscle tone on palpation	duidelijk milde of matige depletie van vetmassa en/of spiermassa en/of spiertonus bij palpatie	"en/of" added after "vetmassa" because it is different from "of"

TABLE 3. Indices for content validity, comprehensibility and difficulty for the patient-generated component of the Dutch PG-SGA as perceived by professionals and patients with cancer

Sample	professionals	patients	Patients
Item	I-CVI (N=8)[1]	I-CI (N=6)[2]	I-DI (N=6)[3]
Box 1: Weight			
1a. I currently weigh about _____ pounds	1.00	1.00	1.00
1b. I am about _____ feet _____ tall	1.00	1.00	1.00
1c. One month ago I weighed about _ pounds	1.00	1.00	1.00
1d. Six months ago I weighed about __ pounds	1.00	1.00	0.83
1e. During the past two weeks my weight has: decreased/ not changed/ increased	0.88	1.00	1.00
Box 2: Food intake			
2a. As compared to my normal intake. I would rate my food intake during the past month as:	1.00	1.00 (N=5)	0.83 (N=5)
2a1. unchanged	1.00	1.00 (N=5)	
2a2. more than usual	0.88	1.00 (N=5)	
2a3. less than usual	1.00	0.83	
2b. I am now taking:	0.86 (N=7)	1.00 (N=5)	1.00 (N=5)
2b1. *normal food* but less than normal amount	0.75	1.00 (N=5)	
2b2. little solid foods	0.86 (N=7)	1.00 (N=5)	
2b3. only liquids	0.88	1.00 (N=5)	
2b4. only nutritional supplements	0.88	1.00 (N=5)	
2b5. very little of anything	0.86 (N=7)	1.00 (N=5)	
2b6. only tube feedings or only nutrition by vein	0.88	1.00	
Box 3: Symptoms			
3a. I have had the following problems that have kept me from eating enough during the past two weeks:	1.00	1.00	1.00 (N=5)
3a1. no problems eating	0.88	1.00	
3a2. no appetite, just did not feel like eating	1.00	1.00	
3a3. Nausea	1.00	1.00	
3a4. Constipation	1.00	1.00	

TABLE 3. Continued

Sample	**professionals**	**patients**	**patients**
Item	I-CVI (N=8)[1]	I-CI (N=6)[2]	I-DI (N=6)[3]
3a5. mouth sores	1.00	1.00	
3a6. things taste funny or have no taste	0.88	1.00	
3a7. problems swallowing	1.00	1.00	
3a8. pain, where?	1.00	1.00	
3a9. Vomiting	1.00	1.00	
3a10. Diarrhea	0.88	1.00	
3a11. dry mouth	0.88	1.00	
3a12. smells bother me	1.00	1.00	
3a13. feel full quickly	1.00	1.00	
3a14. Fatigue	1.00	1.00	
3a15. other: ……..	0.88	1.00	
Box 4. Activities and Function			
4a. Over the past month, I would generally rate my activity as:	1.00	1.00 (N=5)	1.00 (N=5)
4a1. normal with no limitations	1.00	1.00 (N=5)	
4a2. not my normal self, but able to be up and about with fairly normal activities	1.00	1.00 (N=5)	
4a3. not feeling up to most things, but in bed or chair less than half the day	1.00	1.00 (N=5)	
4a4. able to do little activity and spend most of the day in bed or chair	1.00	1.00 (N=5)	
4a5. pretty much bedridden, rarely out of bed	1.00	1.00 (N=5)	
Scale Indices Patient Generated Component	**S-CVI[4]** = 0.95[7]	**S-CI[5]** =0.99[8]	**S-DI[6]** = 0.96[9]
Overall item response	99%	94%	93%

[1]I-CVI: item-content validity index; [2]I-CI: item-comprehensibility index; [3]I-DI: item-difficulty index

[4]S-CVI: scale-content validity index; [5]S-CI: scale-comprehensibility index; [6]S-DI: scale-difficulty index

[7]incl. non-response: 0.94; [8]incl. non response: 0.93; [9]incl. non response: 0.89

I-CVI /I-CI/I-DI>0.78 excellent; S-CVI/S-CI/S-DI>0.80 acceptable; S-CVI/S-CI/ S-DI>0.90 excellent

TABLE 4. Indices for content validity, comprehensibility and difficulty for the professional component of the Dutch PG-SGA as perceived by professionals

Sample	professionals	professionals	professionals
Item	I-CVI (N=8)[1]	I-CI (N=8)[2]	I-DI (N=7)[3]
Worksheet 1: Scoring Weight Loss	0.88	1.00	0.83 (N=6)
Worksheet 2: Disease and its relation to nutritional requirements	1.00	0.88	0.83 (N=6)
2a. All relevant diagnoses	1.00	0.75	0.71
2b. Primary disease stage	1.00 (N= 6)	0.75	0.71
2c. Age	0.86 (N=7)	1.00	1.00
Worksheet 3: Metabolic Demand			
3a. Fever	0.88	0.88	0.71
3b. Fever duration	0.88	0.88	0.71
3c. Corticosteroids	1.00	0.88	0.86
Worksheet 4: Physical Exam	0.29 (N=7)	0.75	0.20 (N=5)
4a. Muscle Status			
4a1. Temples (temporalis muscle)	0.71 (N=7)	0.75	0.40 (N=5)
4a2. Clavicles (pectoralis & deltoids)	0.71 (N=7)	0.75	0.40 (N=5)
4a3. Shoulders (deltoids)	0.86 (N=7)	0.75	0.40 (N=5)
4a4. Interosseous muscles	0.43 (N=7)	0.50	0.17 (N=6)
4a5. Scapula	0.57 (N=7)	0.75	0.40 (N=5)
4a6. Thigh (quadriceps)	0.86 (N=7)	0.75	0.20 (N=5)
4a7. Calf (gastrocnemius)	0.67 (N=6)	0.75	0.20 (N=5)
4b. Fat stores	0.86 (N=7)	0.75	0.20 (N=5)
4b1. Orbital fat pads	0.71 (N=7)	0.75	0.60 (N=5)
4b2. Triceps skinfold	0.86 (N=7)	0.88	0.60 (N=5)
4b3. Fat overlying lower ribs	0.86 (N=7)	0.75	0.20 (N=5)
4c. Fluid status	1.00 (N=7)	0.88	0.60 (N=5)
4c1. Ankle edema	0.57 (N=7)	1.00	0.80 (N=5)

Table 4. Continued

Sample	**professionals**	**professionals**	**professionals**
Item	I-CVI (N=8)[1]	I-CI (N=8)[2]	I-DI (N=7)[3]
4c2. Sacral edema	0.63	0.75	0.60 (N=5)
4c3. Ascites	0.88	0.88	0.60 (N=5)
Worksheet 5 Global Assessment Categories	1.00 (N=6)		0.60 (N=5)
5a. Weight		0.88	
5b. Nutrient intake		0.88	
5c. Nutrition Impact Symptoms		0.88	
5d. Functioning		0.75	
5e. Physical exam		0.88	
Global PG-SGA Rating	1.00 (N=7)	0.75	0.71
Triage 0-1: No intervention required at this time		0.88	
Triage 2-3: Patient & family education		0.75	
Triage 4-8: intervention by dietitian, in conjunction with nurse or physician as indicated by symptoms.		0.88	
Triage ≥9: critical need for improved symptom management and/or nutrient intervention options		0.63	
Scale Indices Professional Component	**S-CVI[4] =** 0.81[7]	**S-CI[5] =** 0.81	**S-DI[6] =** 0.55[8]
Item response Professional Component	90%	100%	81%
Scale Indices Full PG-SGA	**S-CVI[4] =**0.89[9]		
Overall item response	95%		

[1]I-CVI: item-content validity index; [2]I-CI: item-comprehensibility index; [3]I-DI: item-difficulty index; [4]S-CVI: scale-content validity index; [5]S-CI: scale-comprehensibility index; [6]S-DI: scale-difficulty index; [7]incl. non-response: 0.72; [8]incl. non-response: 0.46; [9]incl. non-response: 0.86; I-CVI /I-CI/I-DI>0.78 excellent ; S-CVI/S-CI/S-DI>0.80 acceptable; S-CVI/S-CI/ S-DI>0.90 excellent

The indices for content validity, comprehensibility and difficulty for the patient-generated component and the professional component of the Dutch PG-SGA are presented in Table 3 and Table 4. Content validity of the overall PG-SGA was perceived sufficient for the assessment of malnutrition on scale level (S-CVI: 0.89 [overall item response 95%]). Professionals' individual S-CVI scores ranged from 0.81 to 1.00 for content validity. Cancer patients perceived comprehensibility and level of difficulty of the patient-generated component of the Dutch translation of the PG-GSA as excellent (S-CI: 0.99 [overall item response 94%]; S-DI: 0.96 [overall item response 93%]). Patients' individual S-CI scores ranged from 0.95 to 1.00 for comprehensibility and individual S-DI scores ranged from 0.88 to 1.00 for difficulty. Comprehensibility of the professional component of the PG-SGA was experienced as acceptable on scale level (S-CI: 0.81 [overall item response 100%]). Professionals' individual S-CI scores ranged from 0.44 to 1.00 for comprehensibility. Difficulty of the professional component of the PG-SGA was graded under the predefined cutoff for acceptability on scale level (S-DI: 0.55 [overall item response 81%]). Professionals' individual S-DI scores ranged from 0.39 to 0.89.

The patients' answers to the open ended questions showed that one out of six patients perceived question 2a, “As compared to my normal intake, I would rate my food intake during the past month as: unchanged; more than usual; less than usual” from Box 2 (Food intake) as difficult to answer. Two out of six patients missed answering possibilities that were relevant to them in question 2b, “I am now taking …”. One patient reported that he would have liked to add the following answer: “more food than usual”, and the other patient reported he would have liked to add the option of: “a little solid food and nutritional supplements”. One out of six patients was in frail condition and preferred the dietitian to read the questions and answering possibilities and complete the patient’s answers.

The healthcare professionals' answers to the open ended questions did not reveal any additional aspects of malnutrition that were not measured by the PG-SGA. Six out of eight healthcare professionals had difficulties completing the items concerning the physical examination, because they lacked experience and training regarding the physical exam. Two of these six stated they would need additional training in order to perform this section of the PG-SGA. Six out of eight healthcare professionals considered the elaborateness of the five page template prototype and the time needed to complete the instrument a barrier for them for applying the Dutch PG-SGA in daily practice. Six out of eight healthcare professionals felt that the PG-SGA offers a complete malnutrition assessment.

The proofreading mainly resulted in adaptations of the template of the PG-SGA. The five-page layout was considered a barrier. It should be noted that this format was not consistent with the original template of the PG-SGA, thus the size was confined to two pages A4 size, conforming to the template of the original large print version of the PG-SGA (©2005), using a landscape orientation. Because of these adaptations, on the front page a larger print could be used for the patient-generated component, to improve readability. Professional-generated items and summarized scoring were placed on the back page, conform the template of the 2005 PG-SGA version. The final appropriately formatted version of the Dutch PG-SGA, which has been authorized by the key developer and officially published on www.pt-global.org on 12 August 2014, is presented in Figure 2.[47]

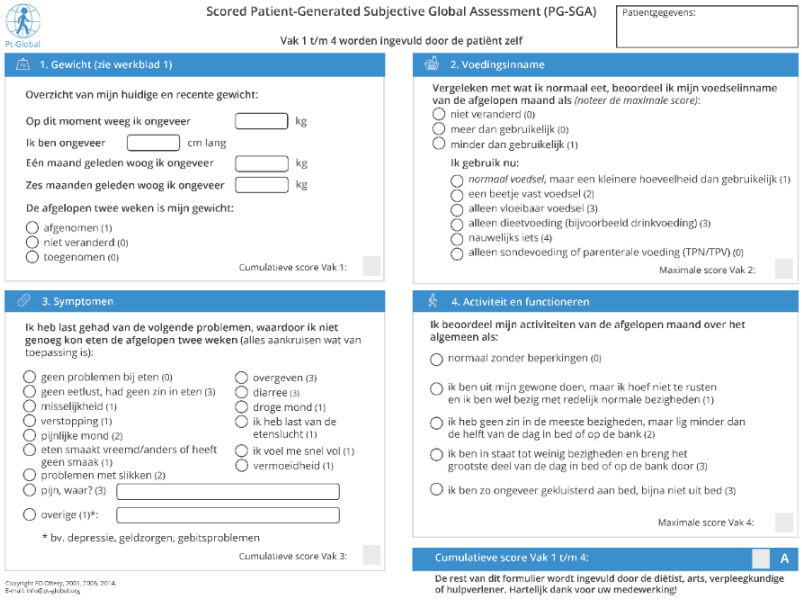

FIGURE 2a. Final Version of the Dutch PG-SGA 12 August 2014: patient component

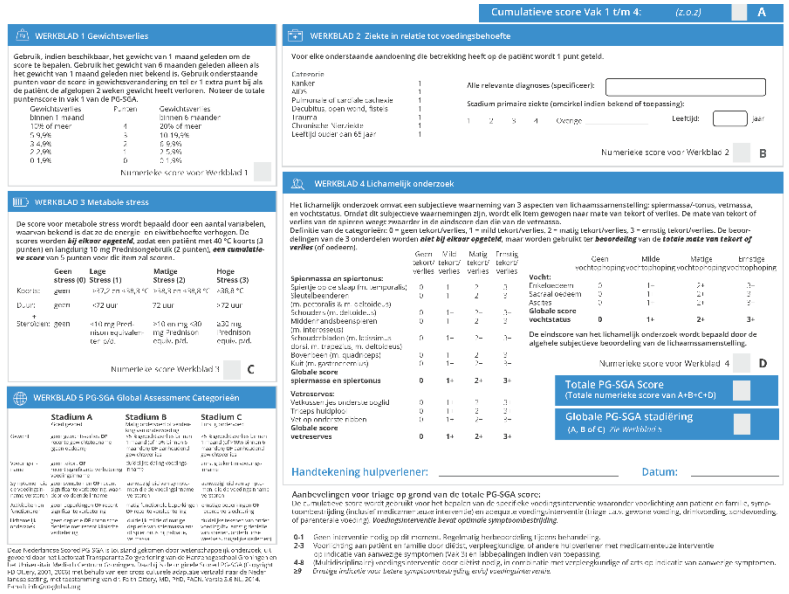

FIGURE 2b. Final Version of the Dutch PG-SGA 12 August 2014: professional component

Discussion

Translation and cultural adaptation of the English PG-SGA (© 2005) according to ISPOR principles resulted in a Dutch version that maintained purpose, meaning and format and has acceptable content validity. Forward and back translation by multiple independent translators, cognitive debriefing in patients and healthcare professionals, and consulting the key developer during the developmental phase enabled safeguarding of conceptual, semantic and operational equivalence.

During the cognitive debriefing, the sample of patients with cancer perceived both comprehensibility and difficulty of the patient-reported component of the prototype version of the Dutch PG-SGA as excellent. This high level of perceived comprehensibility and difficulty suggests feasibility of completion of the patient-generated component, i.e. Boxes 1 to 4, of the PG-SGA or PG-SGA SF by Dutch patients without further instruction. The feasibility of completion of Boxes 1 to 4 by the patient is supported by results from a translation and cultural adaptation study of the PG-SGA that was previously performed for the Brazilian Portuguese setting. In that study in a sample of patients in which 65% had a low education level, a high score for comprehensibility (S-CI >0.80) was reported for all patient-reported items.[44] In our study, two patients suggested additional choices for the item "I am now taking …" in Box 2 (Food intake) in reply to the open ended questions, implying that not all possible alternatives are fully covered in this Box. Although this important observation is noted, adding answering possibilities in the Dutch version at this time is not desirable, as this may affect the PG-SGA score, and thus operational equivalence with the original instrument.

During the exploration of content validity and cognitive debriefing, the sample of PG-SGA naive healthcare professionals perceived content validity, i.e., relevance of the full PG-SGA

(patient-generated plus professional component) to the construct of malnutrition, acceptable on scale level. The healthcare professionals also perceived comprehensibility of the professional component acceptable on scale level. However, the items on the physical examination scored lower for both content validity and comprehensibility. The healthcare professionals scored difficulty of the professional component below acceptable on scale level, of which the items on the physical examination scored lowest. These results for the items of the physical examination suggest that an item perceived as difficult is also at risk to be considered less important, e.g. when knowledge on the subject of the item is lacking, it is also harder to decide whether the item is relevant to the construct. The results for comprehensibility of the physical examination also indicate that if an item is regarded difficult by a respondent, the item is also at risk of being considered harder to comprehend. This may be due to use of vocabulary not suitable to the level of the respondent.[48]

Customized approaches may be appropriate to solve problems related to content validity, comprehensibility, or difficulty of the PG-SGA. Items with low content validity may be improved by adapting the item to adequately represent the construct of malnutrition as perceived in the target culture.[35] Items that lack comprehensibility may be improved by clarifying the formulation of the description of the item, to make this item more understandable. Problems regarding difficulty may be prevented by providing instruction or training, to improve knowledge of the respondent regarding the item.[48] In this study, two items from Worksheet 2: “relevant diagnoses” and “stage of disease” were scored slightly below the cutoff for acceptability by healthcare professionals. Because the problem concerns the concept of comprehensibility, this implies the level of comprehensibility can be improved by clarifying the formulation. To improve comprehensibility for professionals

such as nurses, dietitians and physicians, an additional instruction including further explanation of Worksheet 2 is currently being developed.

The I-DI scores for the physical examination were the most striking, with scores ranging from 0.17 to 0.80, and an average of 0.41. The answers to the open ended questions also suggest the physical exam was perceived difficult by the sample of healthcare professionals that were inexperienced with the PG-SGA. The nature of the concept difficulty implies the level of perceived difficulty can be influenced by improving the level of skill or knowledge. This agrees with the need for further instruction and training regarding the physical examination that was expressed by the healthcare professionals. Since a lack of experience with the physical examination may explain the scores for difficulty, additional training may have a positive effect on professionals' competence to perform the physical examination. The Subjective Global Assessment (SGA)[30] contains the same type of items concerning the physical examination as the PG-SGA. In a study on interrater reliability (IRR) of the SGA, more experienced healthcare professionals (>5 years after graduation) showed an IRR of 89-100% when compared to a well- trained and experienced dietitian (>20 years after graduation), whereas less trained and experienced healthcare professionals (1-2 years after graduation) showed an IRR of 56-100%.[49] To test whether additional instruction improves the level of perceived difficulty and consequently also comprehensibility of the PG-SGA, we developed a training course. The training was tailored to the needs reported by professionals, with emphasis on the physical examination. The effect of this training on perceived comprehensibility and difficulty of the Dutch PG-SGA by healthcare professionals will be reported in a separate article.

Implications for research and practice

The data from this study suggest that translation and cultural adaptation of the PG-SGA according to ISPOR Principles is an effective strategy to maintain purpose, meaning and format of the original PG-SGA. A similar systematic approach for future translations of the PG-SGA into other languages is recommended, to safeguard cultural equivalence of the instrument. Although good concurrent and predictive validity of the original English PG-SGA for assessment of malnutrition and its risk factors have been shown,[18,21,23] further research is needed to explore psychometric characteristics of the Dutch PG-SGA in the Dutch setting. In addition, generalizability of the results to patient groups that were beyond our scope needs to be explored.

The translated and culturally adapted PG-SGA is now available for the Dutch setting and may help facilitate to an efficient, interdisciplinary, and collaborative nutrition care process. Enabling patients to complete the PG-SGA SF at home or in the waiting room addresses in a non-stressful, time flexible but standardized manner a way to address issues that are relevant to the patient and carer, provides an opportunity to save time for the professional, and provides the full interdisciplinary team with information on malnutrition and underlying risk factors. As a result, this may facilitate personalized identification and treatment of impediments and may lead to an improved nutritional care approach with the objective to improve nutritional and other related outcomes. In addition to the PG-SGA SF, the professional component of the PG-SGA can be completed by, for instance, a dietitian, nurse or physician to collect more detailed information. Subsequently, the identification of specific impediments combined with specific nutritional triage

recommendations may help initiating personalized symptom management and/or nutrition intervention.

Strengths and limitations

The strengths of the research include that, in addition to the patient-reported items, the professional-reported items of the PG-SGA were translated and culturally adapted. The ISPOR Principles have been developed and deployed for instruments that contain patient-reported items.[41] However, the PG-SGA additionally contains professional-reported items. By using the ISPOR Principles within the professional-reported section, we came across 62 differences resulting from the two forward translations, and three differences resulting from the two back translations. These differences would not have been noticed with a single forward translation. Cultural equivalence of the professional component of the original instrument might have been affected if these differences had remained unnoticed. Additionally, exploring comprehensibility and difficulty of the professional-reported items of the PG-SGA during the cognitive debriefing resulted in clear information on professionals perceiving difficulty with the physical examination. Hence, following the steps of the ISPOR Principles contributed to the quality of the translated instrument, for both the patient-generated component and the professional component of the PG-SGA.

To the best of our knowledge, this study is the first translation and cultural adaptation study to explore the three concepts content validity, comprehensibility, and difficulty concomitantly, using indices. We were not able to explore conceptual and semantic equivalence with a sample from the source culture, for instance by comparing results of semi-structured interviews with a representative set of patients from the target culture to results of similar interviews with a representative set of patients from the source culture.

Still, an acceptable level of content validity, comprehensibility and difficulty is needed for the instrument to be able to perform accurate measurements.[48] Thus, we decided to quantify perceived content validity, comprehensibility and difficulty, and compare the results to a predefined cutoff value. We found it useful to distinguish between content validity, comprehensibility and difficulty, because the different concepts imply customized approaches to solve problems.

We included healthcare professionals that had no previous experience with the PG-SGA to safeguard unbiased cultural perception of content validity, comprehensibility and difficulty of the instrument. Since healthcare professionals did not receive any instruction prior to the completion of the PG-SGA, lack of experience may have affected the results of this study. For instance, healthcare professionals reported the time needed for completion of the PG-SGA as a barrier, while their own unfamiliarity with the instrument has probably extended the time needed for completion.

The study has some limitations. First, the sample size used to explore content validity, comprehensibility and difficulty was small. Although according to ISPOR Principles the number of six patients can be considered an adequate sample size,[41] the population of patients with cancer is rather heterogeneous, which may call for a somewhat larger sample of patients to cover the breath of the population. However, we attempted to acquire sufficient data density by employing an extensive questionnaire of 47 items and eight open ended questions regarding comprehensibility and difficulty of the patient-generated component of the PG-SGA. In addition, patients and their health care professionals were included in the translation and cultural adaptation process together, which allowed simulating a situation of daily practice. Second, some selection bias in this cognitive debriefing cannot be excluded, as healthcare professionals might have selected motivated

patients or patients with adequate cognitive function to participate in the pilot test. Additionally, level of education was not regarded in this study and underestimation or overestimation of the patients' results due to a lower or higher than average education level in our study cannot be excluded. To confirm the patient-generated results, further testing of the PG-SGA SF in a larger set of randomly selected patients is recommended. Finally, the lay out of the prototype version of the PG-SGA that was used during the cognitive debriefing, was not according the lay out of the 2005 landscape version of the PG-SGA. Importantly, this prototype version of the PG-SGA consisted of five pages and this elaborateness likely extended the time needed for completion.

Conclusion

Translation and cultural adaptation of the PG-SGA according to ISPOR Principles resulted in a Dutch version that maintained purpose, meaning and format and has acceptable content validity. Now a Dutch version of an instrument is available that assesses malnutrition, identifies nutrition impact symptoms and guides interdisciplinary planning of the nutrition care process. The Dutch version of the PG-SGA is considered comprehensible and easy by patients, and comprehensible and relevant by professionals. However, the professional component was considered difficult by the PG-SGA naive professionals, which indicates a need for appropriate training of healthcare professionals. A similar systematic approach for future translations of the PG-SGA is recommended, to safeguard cultural equivalence. Further studies related to the validity and reliability of the Dutch PG-SGA (SF) can now be initiated.

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